EXHIBIT A1

UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF FLORIDA FORT MYERS DIVISION

NATIONAL UNION FIRE INSURANCE COMPANY OF PITTSBURGH, PA., and FEDERAL INSURANCE COMPANY,

<i>Plaintiffs</i> ,	
v.	Case No. 2:22-cv-00226
ARTHREX, INC.,	
Defendant.	
	/

COMPLAINT FOR DECLARATORY RELIEF

National Union Fire Insurance Company of Pittsburgh, Pa. ("National Union") and Federal Insurance Company ("Federal") sue Defendant Arthrex, Inc. ("Arthrex"), and allege:

NATURE OF THE ACTION, JURISDICTION, AND VENUE

- 1. Pursuant to 28 U.S.C. § 2201, this is an action to declare the rights and other legal relations of the parties in relation to insurance policies issued by National Union and Federal to Arthrex and any individuals qualifying as "Insureds" under the policies.
- 2. Arthrex presently claims that it is owed the full \$20,000,000 limits of the applicable insurance policies issued by National Union and Federal.
- 3. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 because the parties between whom there is controversy are completely diverse and the amount in controversy exceeds \$75,000.00, exclusive of interest and costs.

4. Venue is proper in this judicial district and division under 28 USC §1391(b)(3) and M.D. Fla. L.R. 1.04(a) as Arthrex maintains its principal place of business in Collier County, Florida.

THE PARTIES

- 5. National Union is an insurance company incorporated under the laws of the Commonwealth of Pennsylvania with its principal place of business in New York, and is thus a citizen of Pennsylvania and New York.
- 6. Federal is an insurance company incorporated under the laws of the state of Indiana, with its principal place of business in New Jersey, and is thus a citizen of Indiana and New Jersey.
- 7. Arthrex is a medical device company incorporated under the laws of the State of Delaware with its headquarters and principal place of business in Naples, Florida, and thus is a citizen of Florida and Delaware.

THE POLICIES

- 8. National Union issued a PrivateEdge Plus Insurance Policy to Arthrex, bearing Policy No. 01-340-76-97, for the Policy Period of April 26, 2019 to April 26, 2020 and a Limit of Liability of \$10,000,000 (the "Primary Policy"), which includes Directors, Officers and Private Company Liability Insurance.
 - 9. **Exhibit A** is a true and correct copy of the Primary Policy.
- 10. Federal issued a Directors and Officers Liability Excess Chubb Policy, bearing Policy No. 8240-1243 (the "Excess Policy"), and a Limit of Liability of \$10,000,00, which is excess to the Primary Policy's limit.

- 11. The Excess Policy follows form to and adopts the terms, conditions and limitations of the Primary Policy.
 - 12. **Exhibit B** is a true and correct copy of the Excess Policy.
- 13. Together, National Union and Federal are referred to as "the Insurers," and the Primary Policy and the Excess Policy are referred to as "the Policies."
- 14. In relevant part, the D&O Section of the Primary Policy includes the following language:

1. INSURING AGREEMENTS

COVERAGE B: PRIVATE COMPANY INSURANCE

- (i) **Company** Liability: This policy shall pay the **Loss** of any **Company** arising from a **Claim** made against such **Company** for any **Wrongful Act** of such **Company**.
- (ii) *Indemnification of an* **Individual Insured**: This policy shall pay the **Loss** of a **Company** arising from a:
 - (a) Claim made against an Individual Insured for any Wrongful Act of such Individual Insured; and
 - (b) **Pre-Claim Inquiry**, to the extent that such **Loss** is either Pre-**Claim Inquiry Costs** or **Liberty Protection Costs**;

but only to the extent that such **Company** has indemnified such **Individual Insured**.

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2. **DEFINTIONS**

(b) "Claim" means:

(i) a written demand for monetary, non-monetary or injunctive relief (including any request to toll or waive any statute of limitations);

- (ii) a civil, criminal, administrative, regulatory or arbitration proceeding for monetary, non-monetary or injunctive relief which is commenced by:
 - (1) service of a complaint or similar pleading;
 - (2) return of an indictment, information or similar document (in the case of a criminal proceeding); or
 - (3) receipt or filing of a notice of charges; or
 - (iii) a civil, criminal, administrative or regulatory investigation of an **Individual Insured**:
 - (1) once such **Individual Insured** is identified in writing by such investigating authority as a person against whom proceeding described in Definition 2(b)(ii) may be commenced; or
 - (2) in the case of an investigation by the Securities Exchange Commission ("**SEC**") or a similar state or foreign government authority, after:
- (a) the service of a subpoena upon such **Individual Insured** . . .

* * *

(k) "Defense Costs" means the reasonable and necessary fees, costs and expenses consented to by the Insurer (including premiums for any appeal bond, attachment bond or similar bond arising out of a covered judgment, but without any obligation to apply for or furnish any such bond), resulting solely from the investigation, adjustment, defense and appeal of a Claim against an Insured, but excluding compensation of any Individual Insured. Defense Costs shall not include any fees, costs or expenses incurred prior to the time that a Claim is first made against an Insured.

"Defense Costs" shall not include Pre-Claim Inquiry Costs.

* * *

"Loss" means damages, judgments, settlements, pre-(u) judgment and post-judgment interest, Crisis Management **Loss** and **Defense Costs**; provided, however, **Loss** shall not include: (i) civil or criminal fines or penalties imposed by law; (ii) taxes; (iii) any amounts for which an **Insured** is not financially liable or which are without legal recourse to an **Insured**; or (iv) matters which may be deemed uninsurable under the law pursuant to which this policy shall be construed. Notwithstanding the foregoing subparagraph (iv), the **Insurer** shall not assert that, in a **Securities Claim** alleging violations of Section 11, 12 or 15 of the Securities Act of 1933, as amended, the portion of any amounts incurred by **Insureds** which is attributable to such violations constitutes uninsurable loss and shall treat that portion of all such settlements, judgments and **Defense Costs** as constituting **Loss** under this policy.

Defense Costs shall be provided for items specifically excluded from **Loss** pursuant to subparagraphs (u)(i) through (u)(iv) above of this Definition, subject to the other terms, conditions and exclusions of this policy.

Loss shall specifically include, subject to the other terms, conditions and exclusions of this **D&O Coverage Section**, including, but not limited to, exclusions 4(a), 4(b) and 4(c) of this **D&O Coverage Section**, punitive, exemplary and multiple damages. As more fully set forth in Clause 5. "LIMIT OF LIABILITY" of this **D&O Coverage Section**, coverage under this **D&O Coverage Section** for punitive, exemplary and multiple damages is subject to any applicable **D&O Punitive Damages Sublimit of Liability** or **Shared Punitive Damages Sublimit of Liability**. The enforceability of the first sentence of this paragraph shall be governed by such applicable law which most favors coverage for punitive, exemplary and multiple damages.

Loss includes **Pre-Claim Inquiry Costs**.

"Loss" shall also include, subject to the other terms, conditions and exclusions of this **D&O** Coverage Section, including, but not limited to, exclusions 4(a), 4(b) and 4(c) of this **D&O** Coverage Section, civil penalties assessed against any individual director or officer pursuant to Sections

2(g)(2)(B) of the Foreign Corrupt Practices Act, 15 U.S.C. § 78dd-2(g)(2)(B).

* * *

(cc) "Wrongful Act" means:

- (i) with respect to any Executive or Employee of a Company, any breach of duty, neglect, error, misstatement, misleading statement, omission or act by such Executive or Employee in their respective capacities as such, or any matter claimed against such Executive or Employee of a Company solely by reason of his or her status as an Executive or Employee of a Company;
- (ii) with respect to a Company, any breach of duty, neglect, error, misstatement, misleading statement, omission or act by a Company;

* * *

6. NOTICE/CLAIM REPORTING PROVISIONS

Notice hereunder shall be given in writing to the addressee and at the address identified in Item 9(b) of the Declarations. Notice shall include and reference this policy number as indicated in the Declarations, as well as the **Coverage Sections** under which the **Claim** is being noticed. If mailed, the date of mailing shall constitute the date that such notice was given and proof of mailing shall be sufficient proof of notice.

The following shall apply:

- (a) An **Insured** shall, as a condition precedent to the obligations of the **Insurer** under this policy:
 - (1) give written notice to the **Insurer** of a **Claim** made against an **Insured** or a **Crisis Management Event**; or
 - (2) if an **Insured** elects to seek coverage for **Pre-Claim Inquiry Costs** in connection with any **Pre-Claim Inquiry**, give written notice to the **Insurer** of that **Pre-Claim Inquiry**;

as soon as practicable after (i) the **Named Entity's** Risk Manager or General Counsel (or equivalent position) first becomes aware of the **Claim** or **Pre-Claim Inquiry**; or the Crisis Management Event commences. In all such events, notification must be provided no later than 90 days after the end of the **Policy Period** or the **Discovery Period** (if applicable).

(b) If written notice of a **Claim** has been given to the **Insurer** pursuant to Clause 6(a) above, then a **Claim** which is subsequently made against an **Insured** and reported to the **Insurer** alleging, arising out of, based upon or attributable to the facts alleged in the **Claim** for which such notice has been given, or alleging a **Wrongful Act** that is a **Related Wrongful Act** to any **Wrongful Act** either alleged in the **Claim**, of which such notice has been given, shall be considered made at the time the first **Claim** was made.

If a **Pre-Claim Inquiry** was first received by an **Insured** and reported in accordance with Clause 6(a) above, then:

- (1) any **Related Pre-Claim Inquiry** that is reported in accordance with Clause 6(a) above shall be deemed to be a **Pre-Claim Inquiry** first received at the time that such previously reported **Pre-Claim Inquiry** was first received by an **Individual Insured**; and
- (2) any subsequent **Claim** alleging, arising out of, based upon or attributable to any facts or **Wrongful Acts** that are the same as or related to those that were the subject of another **Pre-Claim Inquiry** received by an **Insured** that is reported in accordance with Clause 6(a) above shall be deemed to be a **Claim** first made at the time that such previously reported **Pre-Claim Inquiry** was first received by an **Insured**.

With respect to any subsequent **Related Pre-Claim Inquiry**, this policy shall not cover **Loss** incurred before such subsequent **Related Pre-Claim Inquiry** is actually received by an **Individual Insured**, and with respect to any subsequent **Claim** as described in this paragraph (b), this policy shall not cover **Loss** incurred before such subsequent **Claim** is actually made against an **Insured**.

(c) If during the **Policy Period** or during the **Discovery Period** (if applicable) the **Insureds** shall become aware of any circumstances which may reasonably be expected to give rise to a **Claim** being made against the **Insureds** and shall give written notice to the **Insurer** of the circumstances, the **Wrongful Act** allegations anticipated and the reasons for anticipating such a **Claim**, with full particulars as to dates, persons and entities involved, then any **Claim** which is subsequently made against the **Insureds** and reported to the **Insurer** alleging, arising out of, based upon or attributable to such circumstances or alleging any **Wrongful Act** which is the same as or is a **Related Wrongful Act** to that alleged or contained in such circumstances, shall be considered made at the time such notice of such circumstances was given.

* * *

7. DEFENSE COSTS, SETTLEMENTS, JUDGMENTS (INCLUDING THE ADVANCEMENT OF DEFENSE COSTS)

The **Insurer** does not assume any duty to defend. The **Insureds** shall defend and contest any **Claim** made against them.

Notwithstanding the foregoing, the **Insureds** shall have the right to tender the defense of the **Claim** to the **Insurer**, which right shall be exercised in writing by the **Named Entity** on behalf of all **Insureds** to the **Insurer** pursuant to the notice provisions of Clause 12 of the **General Terms and Conditions**. This right shall terminate if not exercised within thirty (30) days of the date the **Claim** is first made against an **Insured**. Further, from the date the Claim is first made against an Insured to the date when the **Insurer** accepts the tender of the defense of such **Claim**, the **Insureds** shall take no action, or fail to take any required action, that prejudices the rights of any **Insured** or the **Insurer** with respect to such **Claim**. Provided that the **Insureds** have complied with the foregoing, the **Insurer** shall be obligated to assume the defense of the Claim, even if such Claim is groundless, false or fraudulent. The assumption of the defense of the **Claim** shall be effective upon written confirmation sent thereof by the **Insurer** to the **Named Entity**. Once the defense has been so tendered, the **Insured** shall have the right to effectively associate with the Insurer in the defense and the negotiation of any settlement of any **Claim**, subject to the provisions of this Clause 7; provided, however, the **Insurer** shall not be obligated to defend such **Claim** after the **Policy Aggregate Limit of Liability** or any applicable **Separate Limit of Liability** or **Shared Limit of Liability** have been exhausted.

Once the **Insurer** has received written notice of a **Claim** for which the **Insurer** has not assumed the defense or a **Pre-Claim Inquiry**, the **Insurer** nevertheless shall advance, excess of any applicable Retention, **Defense Costs** or **Pre-Claim Inquiry Costs**, respectively, on a current basis, but no later than 90 days after the **Insurer** has received itemized bills for those **Defense Costs** or **Pre-Claim Inquiry Costs**. Such advanced payments by the **Insurer** shall be repaid to the **Insurer** by each and every **Insured** or the **Company**, severally according to their respective interests, in the event and to the extent that any such **Insured** or the **Company** shall not be entitled under the terms and conditions of this **D&O Coverage Section** to payment of such **Loss**.

The **Insurer** shall have the right to fully and effectively associate with each and every **Insured** in the defense of any **Claim** or **Pre-Claim Inquiry** that appears reasonably likely to involve the **Insurer**, including, but not limited to, negotiating a settlement. Each and every **Insured** agrees to provide such information as the **Insurer** may reasonably require and to give the **Insurer** full cooperation, including:

- (a) cooperating with and helping the **Insurer**:
 - (i) in making settlements, subject to subparagraph 7(b) below;
 - (ii) in enforcing any legal rights the **Insured** may have against anyone who may be liable to the **Insured**;
 - (iii) by attending depositions, hearings and trials; and
 - (iv) by securing and giving evidence, and obtaining the attendance of witnesses; and
- (b) taking such actions which, in such **Insured's** judgment, are deemed necessary and practicable to prevent or limit **Loss** arising from any **Wrongful Act**.

Additionally, the **Insured** shall not admit or assume any liability, enter into any settlement agreement, stipulate to any judgment, or incur any **Defense Costs** without the prior written consent of the **Insurer**. If the **Insured** admits or assumes any liability in connection with any Claim or Pre-Claim Inquiry without the consent of the **Insurer**, then the **Insurer** shall not have any obligation to pay **Loss** with respect to such **Claim** or **Pre-Claim Inquiry**. Only those settlements, stipulated judgments, **Defense Costs** and **Pre-Claim Inquiry Costs** which have been consented to by the **Insurer** shall be recoverable as **Loss** under the terms of this **D&O Coverage Section**. The **Insurer** shall not unreasonably withhold any consent required under this **D&O** Coverage **Section**, provided that the **Insurer**, when it has not assumed the defense of a **Claim** pursuant to this Clause 7, shall be entitled to effectively associate in the defense and the negotiation of any settlement of any **Claim**, and provided further that in all events the **Insurer** may withhold consent to any settlement, stipulated judgment or **Defense Costs** or **Pre-Claim Inquiry Costs**, or any portion thereof, to the extent such **Loss** is not covered under the terms of this **D&O Coverage Section**. In addition, the **Insured** shall not take any action, without the **Insurer's** written consent, which prejudices the **Insurer's** rights under this **D&O Coverage** Section.

This Clause 7 shall not be applicable to **Crisis Management Loss** or Personal Reputation Expenses.

BACKGROUND FACTS

- 15. The United States Department of Justice ("DOJ") began investigating Arthrex concerning its compensation of certain surgeons in or around January 2020.
- 16. The DOJ served Arthrex with two Subpoenas *Duces Tecum*, dated January 8, 2020 (the "January 8, 2020 Subpoena") and February 7, 2020 (the "February 7, 2020 Subpoena") (collectively, "Subpoenas *Duces Tecum*").

- 17. The Subpoenas *Duces Tecum* stated that Arthrex was required to produce certain documents relating to the DOJ's investigation of potential "Federal health care offenses" as defined in several federal criminal statutes under Title 18, U.S. Code.
- 18. A true and correct copy of the January 8, 2020 Subpoena is attached as **Exhibit C.**
- 19. A true and correct copy of the February 7, 2020 Subpoena is attached as **Exhibit D.**
 - 20. The Subpoenas *Duces Tecum* were directed to Arthrex, Inc.
 - 21. The Subpoenas *Duces Tecum* were not directed to any individual.
- 22. The January 8, 2020 Subpoena requested that Arthrex produce copies of the following: (i) all documents from January 1, 2013 relating to all royalties, consulting fees, and other remuneration Arthrex has paid to any physician or entity owned or controlled by a physician or physicians; (ii) all documents that Arthrex produced in connection with an action captioned *Joseph B. Shea v. Peter Millet and ALM Research, LLC*, Civil Action No. 17-cv-12233-ADB (D. Mass.); (iii) all communications with or concerning Dr. Millet or ALM Research, LLC, an entity owned and controlled by Dr. Millet, from January 1, 2010 to the present; and (iv) all documents from January 1, 2010 to the (then) present relating to Arthrex's policies concerning the anti-kickback statute, and its payment of royalties, consulting fees, and other remuneration to physicians.

- 23. The First Amended Complaint and Jury Trial Demand filed in the action captioned *Joseph B. Shea v. Peter Millet and ALM Research, LLC*, Civil Action No. 17-cv-12233-ADB (D. Mass.) contains the following allegations:
- a. Millett, an orthopedic surgeon residing in Colorado, contributed to the development of medical products related to shoulder surgery. *See* Amended Complaint, ¶¶ 2, 5, 17-18 (attached as **Exhibit E**);
- b. Millett unsuccessfully sought for years to obtain a royalty agreement with Arthrex, a medical device and research company. *Id.* \P 20;
- c. In 2010, Millett approached Shea, a Massachusetts resident and former sales representative of Arthrex, to request Shea's assistance in brokering a royalty agreement between Millett and Arthrex. *Id.* ¶¶ 1, 21-22;
- d. Millett offered Shea 15% of any royalties paid by Arthrex for five years in exchange for Shea's services. *Id.* \P 22;
- e. Shea responded that he would only accept an arrangement in which he would be compensated throughout the life of any royalty agreement he brokered, and proposed instead that he receive 10% of all royalties over the life of any potential royalty agreement between Arthrex and Millett. *Id.* ¶ 23;
- f. Millett accepted Shea's proposal, and Shea proceeded to market Millett's product to several medical device firms that were competitors of Arthrex. *Id.* ¶¶ 23, 32-36;
- g. Ultimately, as a result of Shea's efforts, Arthrex entered into a royalty agreement with Millett. *Id.* \P 42.

- 24. The February 7, 2020 Subpoena requested that Arthrex produce documents from January 1, 2010 to the (then) present concerning the services provided to Arthrex by certain physicians named therein, and all communications with Reinhold Schmeiding and John Schmeiding concerning the payment of royalties, consulting fees, and other remuneration that Arthrex paid or considered paying to a physician or that a physician sought from Arthrex.
- 25. In or about February 2020, Arthrex provided notice of the Subpoenas *Duces Tecum* to National Union, and sought coverage under the Policies in connection with DOJ's investigation.
- 26. The Subpoenas *Duces Tecum* are not Claims as defined under the Primary Policy.
- 27. The Subpoenas *Duces Tecum* do not identify a Wrongful Act as defined in the Primary Policy.
- 28. In response to Arthrex's request for coverage, letters were issued on behalf of National Union to Larry Glick, Senior Associate General Counsel for Arthrex, and John Schmeiding, Senior Vice President and General Counsel for Arthrex, dated April 17, 2020 and April 21, 2020 respectively, advising that the Subpoenas *Duces Tecum* do not meet the definition of Claim as defined by the Primary Policy.
- 29. National Union's April 17, 2020 and April 21, 2020 letters also advised Arthrex that, although the Subpoenas *Duces Tecum* were not Claims as defined by the Primary Policy, National Union accepted the Subpoenas *Duces*

Tecum as a notice of circumstances which might give rise to a Claim in the future, pursuant to Paragraph 6(c) of the General Terms and Conditions of the Primary Policy.

- 30. National Union's April 17, 2020 and April 21, 2020 letters advised Arthrex that in the event that a subsequent Claim is asserted against an Insured, as defined within the Primary Policy, Arthrex should forward such information, documents, or pleadings as quickly as possible, so that the materials could be reviewed for possible coverage under the Primary Policy.
- 31. A true and correct copy of the April 17, 2020 letter is attached as **Exhibit F**.
- 32. A true and correct copy of the April 21, 2020 letter is attached as **Exhibit G.**
 - 33. Arthrex disputed National Union's position.

THE SETTLEMENT

- 34. On February 18, 2021, Arthrex verbally advised National Union that the DOJ made a verbal settlement demand between \$30 million and \$50 million. Arthrex did not provide any other details regarding the proposed settlement.
- 35. Even though Arthrex failed to describe exactly what it was settling with the DOJ, it nevertheless sought National Union's consent to settle.
 - 36. National Union reminded Arthrex that it had not submitted a Claim.
- 37. Later on February 18, 2021, Arthrex sent an email stating that its dispute with the DOJ was the result of multiple "Claims," including, but not

necessarily limited to, the Subpoenas *Duces Tecum* and a *qui tam* complaint (the "*Qui Tam* Complaint") that defense counsel believed was pending.

- 38. On February 19, 2021, National Union responded, in part, as follows: "Your email does not specify precisely what Arthrex is seeking that the Insurers consent to. Based on our discussion yesterday, we presume that you are asking the Insurers to consent to an unspecified settlement offer by Arthrex to the government or agree to waive lack of consent as a coverage defense to any such offer."
- 39. Arthrex did not provide National Union with any documents reflecting the Claim in February 2021.
- 40. National Union did not consent to any settlement offers that Arthrex was contemplating in February 2021.
- 41. National Union did not agree to waive lack of consent for any settlement offers that Arthrex was contemplating in February 2021.
- 42. By email dated March 8, 2021, Arthrex advised it had reached a "preliminary agreement" with the DOJ for \$16 million.
- 43. Other than the settlement amount, Arthrex never disclosed any of the terms of the preliminary agreement to the Insurers.
- 44. On October 27, 2021, counsel for Arthrex advised that "Arthrex is providing a 'heads up' that it believes that a final resolution and public announcement of the underlying settlement are imminent. The government has

set an early November deadline for final resolution, and Arthrex does not expect the government to extend the deadline any further. As such, Arthrex anticipates the settlement to be finalized shortly."

- 45. At the time of its counsel's October 27, 2021 email, Arthrex had not disclosed any of the terms of the settlement it was negotiating with the DOJ to the Insurers.
- 46. On November 4, 2021, Arthrex executed a Settlement Agreement with the DOJ (the "Settlement Agreement").
- 47. On November 8, 2021, counsel for Arthrex advised the Insurers that it "just received word that the government circulated its signed copy of the Agreement this morning. We anticipate providing AIG and Chubb copies of same, the invoices, and other claim-related documents shortly."
- 48. Ten days later, on November 18, 2021, Arthrex first provided the Insurers with copies of the unsealed *Qui Tam* Complaint and Settlement Agreement.
- 49. A true and correct copy of the *Qui Tam* Complaint is attached as **Exhibit H**.
- 50. A true and correct copy of the Settlement Agreement with the DOJ is attached as **Exhibit I**.

- 51. Between the March 8, 2021 "preliminary agreement" and November 18, 2021, Arthrex did not provide the Insurers with a draft of the Settlement Agreement with the DOJ.
- 52. Between the March 8, 2021 "preliminary agreement" and November 18, 2021, Arthrex did not provide the Insurers with a copy of the *Qui Tam* Complaint.
- 53. Arthrex's defense counsel Sidley Austin ("Sidley") reviewed the *Qui Tam* Complaint in March 2021.
- 54. Arthrex was in receipt of the *Qui Tam* Complaint on March 8, 2021 and waited over eight months before providing the *Qui Tam* Complaint to the Insurers.
- 55. The first time Arthrex provided the Insurers with written notice of a Claim made against Arthrex was on November 18, 2021 when it provided the *Qui Tam* Complaint.
- 56. Providing written notice of a Claim is a condition precedent to the Insurers' obligations as set forth in the Primary Policy.
- 57. The *Qui Tam* Complaint states, in part, "[i]n 2010 Dr. Millet contracted with Mr. Shea to represent him in negotiations with Arthrex regarding a royalty agreement. In the course of that contract, Mr. Shea learned that Arthrex's royalty payments are based on the intent to induce referrals of its

products in violation of the federal and state false claims acts." *See* Exhibit H, (*Qui Tam* Complaint Complaint), ¶ 11.

- 58. The *Qui Tam* Complaint sought "civil penalty for each FCA violation" and an order "to disgorge all sums by which" Arthrex was "enriched unjustly."
- 59. The Settlement Agreement states, in part: "the United States contends that Arthrex provided illegal remuneration to Millett, an orthopedic surgeon, to induce him to purchase, order, or recommend the purchasing or ordering of Arthrex medical devices during the period from August 2010 through March 5, 2021 (the 'Relevant Period'). The United States contends that Arthrex entered into a royalty agreement with Millett in August 2010, pursuant to which Arthrex agreed to pay Millett ostensibly for his contributions to the development of the SutureBridge and SpeedBridge kits—two Arthrex product lines that surgeons use in joint repair surgery. In 2006, Arthrex had denied Millett's request for such royalties. The United States contends that when Millett threatened to realign his loyalty to an Arthrex competitor in 2010, Arthrex not only acquiesced to Millett's royalty request but also agreed to pay him royalties for past and future sales of SutureBridge and SpeedBridge kits at a higher percentage rate than was the company's ordinary royalty practice. Pursuant to this agreement, Arthrex paid Millett millions of dollars during the Relevant Period. The United States contends that one purpose of Arthrex's payments was to induce Millett to purchase, order, or recommend the purchasing or ordering of Arthrex medical devices. The United States' contentions as described in this

paragraph are referred to below as the 'Covered Conduct.'" *See* Exhibit I, (Settlement Agreement), Recital C.

- 60. The Settlement Agreement was entered into by the DOJ on behalf of the Office of Inspector General of the Department of Health and Human Services ("OIG-HHS"), relator Joseph P. Shea, and Arthrex.
- 61. The Settlement Agreement provides that in consideration of the obligations of Arthrex as set forth therein, the Corporate Integrity Agreement entered into between OIG-HHS and Arthrex, and upon the receipt of full payment of the settlement amount, "the OIG-HHS shall release and refrain from instituting, directing, or maintaining any administrative action seeking exclusion from Medicare, Medicaid, and other Federal health care programs..." *See* Exhibit I, (Settlement Agreement), ¶ 5.
- 62. The Settlement Agreement provides that "Arthrex shall pay to the United States \$16,000,000, plus interest accruing at an annual rate of 1.375% per annum from March 5, 2021, and continuing until and including the day of payment ('Settlement Amount').... Of the Settlement Amount, \$8,000,000 is restitution to the United States." *See id.*, ¶ 1.
- 63. The amounts described in the Settlement Agreement do not constitute insurable Loss under the Primary Policy.
- 64. The Primary Policy expressly carves out of the definition of Loss both "civil or criminal fines or penalties imposed by law" and "matters which may be

deemed uninsurable under the law pursuant to which this policy shall be construed."

- 65. The Settlement Agreement, which resolved the *qui tam* action, is not covered under the Primary Policy.
- 66. There is a *bona fide* real and actual controversy between the Insurers and Arthrex pertaining to coverage under the Primary Policy.
 - 67. The Insurers have no adequate remedy at law.
- 68. All conditions precedent to filing this action have been satisfied or waived.

FIRST CLAIM FOR DECLARATORY RELIEF

(Declaration That There Is No Coverage For The Subpoena *Duces Tecum*)

- 69. The Insurers reallege and incorporate by reference the allegations made in paragraphs 1 through 68 of this Complaint For Declaratory Relief.
- 70. The Subpoenas *Duces Tecum* are not Claims, as defined under the Primary Policy.
- 71. The Subpoenas *Duces Tecum* are not written demands for monetary or non-monetary relief.
- 72. The Subpoenas *Duces Tecum* are not civil, criminal, administrative, regulatory, or arbitration proceedings, for monetary or non-monetary relief.
- 73. The Subpoenas *Duces Tecum* are not directed at an Individual Insured.

- 74. The Subpoenas *Duces Tecum* do not identify any Individual Insured in writing as a person against whom a proceeding may be commenced.
- 75. The Subpoenas *Duces Tecum* do not identify a Wrongful Act, as that term is defined in the Primary Policy.
- 76. The Insurers have no duty to reimburse Arthrex for Defense Costs incurred in connection with the Subpoenas *Duces Tecum*.

SECOND CLAIM FOR DECLARATORY RELIEF

(Declaration That There is No Coverage for the *Qui Tam* Action and Settlement)

- 77. The Insurers reallege and incorporate by reference the allegations made in paragraphs 1 through 68 of this Complaint For Declaratory Relief.
- 78. The first time that Arthrex reported a Claim to the Insurers was on November 18, 2021, when Arthrex provided National Union with the *Qui Tam* Complaint.
- 79. Arthrex did not begin incurring Defense Costs (as defined by the Primary Policy) until November 18, 2021, the date the Claim was reported to the Insurers.
- 80. Arthrex did not provide the Insurers with the Settlement Agreement until after it was executed.
- 81. The first time the terms of the Settlement Agreement were disclosed to the Insurers was when Arthrex first provided them with a copy of the executed Settlement Agreement on November 18, 2021.

- 82. Arthrex failed to comply with Clause 7 of the D&O Coverage Section of the Primary Policy.
- 83. Arthrex never sought, nor obtained the Insurers' consent to the Settlement Agreement or the Settlement Amount.
- 84. Only Defense Costs and settlements that have been consented to in writing by National Union are potentially covered.
- 85. Arthrex failed to give the Insurers its full cooperation as required under Clause 7 of the D&O Coverage Section of the Primary Policy.
- 86. Arthrex failed to cooperate with the Insurers when it negotiated the settlement and made settlement offers.
- 87. Arthrex deprived the Insurers of their right to fully and effectively associate in the defense of a Claim that appeared reasonably likely to involve them, including, but not limited to, negotiating a settlement.
- 88. Moreover, civil or criminal fines or penalties and matters which may be deemed uninsurable under the law pursuant to which the Policies shall be construed are carved out of the definition of Loss, as that term is defined under the Policy.
- 89. The Settlement Amount is comprised of penalties and uninsurable restitution.
- 90. The Insurers have no duty to indemnify Arthrex for the Settlement Agreement or Settlement Amount.

PRAYER FOR RELIEF

National Union and Federal request that the Court enter judgment in their favor and against Arthrex as follows:

- a. A judgment declaring that National Union and Federal have no duty to reimburse Arthrex for Defense Costs incurred in connection with the Subpoenas *Duces Tecum* because the Subpoenas *Duces Tecum* do not constitute a Claim under the Policy.
- b. A judgment declaring that National Union and Federal have no duty to indemnify Arthrex for the Settlement Amount or to reimburse Arthrex for Defense Costs incurred in connection with negotiating the Settlement Agreement because Arthrex did not report the Claim (the *Qui Tam* Complaint) to National Union and Federal until after it entered into the Settlement Agreement, and it never obtained National Union's and Federal's prior written consent.
- c. A judgment declaring that National Union and Federal have no duty to indemnify Arthrex for the Settlement Amount or to reimburse Arthrex for Defense Costs incurred in connection with negotiating the Settlement Agreement because Arthrex failed to comply with the reporting requirements of the Policy, which are a condition precedent to coverage.
- d. A judgment declaring that National Union and Federal have no duty to indemnify Arthrex for the Settlement Agreement or reimburse Arthrex for Defense Costs incurred in connection with negotiating the Settlement

Agreement because the Settlement Amount is uninsurable as a matter of law and under the Policies.

- e. That National Union and Federal be awarded their fees and costs pursuant to any applicable rule or statute.
- f. That the Court grant such other relief as deemed just and proper.

Dated: April 10, 2022

s/ Aaron S. Weiss

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